UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

EMBER MADSEN,	)	
Plaintiff,	)	
vs.	)	Case No. 4:02CV01835 ERW
AMERICAN HOME PRODUCTS CORPORATION, et al.	)	
Defendant.	)	

MEMORANDUM AND ORDER

This matter comes before the Court upon Plaintiff's Motion to Remand [doc. #51] and Defendant American Home Product Corporation's Motion for Summary Judgment [doc. #40].

I. BACKGROUND FACTS

Plaintiff Ember Madsen ("Plaintiff") filed this products liability action in January 2002 against Defendants American Home Products Corporation; Wyeth-Ayerst Laboratories Company; A.H. Robins Company, Incorporated; Interneuron Pharmaceuticals, Inc.; Walgreen Company; WalMart Stores, Incorporated; and The Medicine Shoppe International, Incorporated.[1] Plaintiff is a citizen of the Commonwealth of Pennsylvania. In June 2001, Wyeth-Ayerst Laboratories Company ("WALCO") merged into American Home Products Subsidiary Holding Corporation ("AHPSHC") and no longer exists as a separate entity. AHPSHC is a citizen of Delaware.

Wyeth Laboratories Company, a pharmaceutical drug company, distributed the

[1] On November 15, 2006, Plaintiff voluntarily dismissed all claims against Defendants Interneuron Pharmaceuticals, Inc.; Walgreen Company; Wal-Mart Stores, Inc.; and the Medicine Shoppe International, Inc.

drugs phentermine, fenfluramine (Pondimin)[2] and dexfenfluramine (Redux)[3] (collectively, "diet drugs") for the treatment of obesity. In August 1997, the Mayo Clinic publicized reports of primary pulmonary hypertension and valvular heart disease in patients who had taken fenfluramine in combination with phentermine.[4] Based on the information from the Mayo Clinic, in July 1997, the United States Food and Drug Administration ("FDA") issued a public health advisory notifying health care professionals of reports of valvular heart disease in women treated for obesity with a combination of fenfluramine and phentermine. Wyeth withdrew the diet drugs from the world market on September 15, 1997.

Plaintiff was prescribed fenfluramine and dexfenfluramine by Timothy J. Miller, M.D. ("Dr. Miller") in 1996, for the treatment of obesity.[5] She consumed the drugs for five months. In June 2000, Prakash Bontu, M.D. ("Dr. Bontu") diagnosed Plaintiff with mild to moderate mitral valve regurgitation. Plaintiff contends that Defendant American Home Products Corporation ("Defendant") knew about the dangers of its diet drugs for a number of years prior to 1996, but failed to share this information with the medical community. Specifically, Plaintiff claims that, in 1993, Defendant was notified of a European study linking fenfluramine with valvular heart disease. Plaintiff also claims Defendant received "adverse drug event" reports associating valvular

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[2] Pondimin is Wyeth's trade name for the drug fenfluramine.

[3] Redux is Wyeth's trade name for the drug dexfenfluramine.

[4] When fenfluramine was prescribed in combination with the drug phentermine, it was commonly referred to as phen-fen.

[5] Plaintiff moved to the Commonwealth of Pennsylvania in November 2001. Prior to that she lived in the State of Iowa for approximately twenty years. Dr. Miller prescribed Pondimin and Redux to Plaintiff in Iowa. Plaintiff also filled her Pondimin and Redux prescriptions in Iowa.

heart disease with the diet drugs from 1994 to 1996. Plaintiff alleges that at the time she ingested fenfluramine and dexfenfluramine, the diet drugs' labels did not mention a risk of valvular heart disease.

In January 2002, Plaintiff filed this action in the St. Louis City Circuit Court alleging six claims against Defendant: 1) breach of warranty; 2) strict liability-defective design; 3) strict liability-failure to warn; 4) negligence;[6] 5) violation of the Deceptive Trade Practices Act; and 6) fraud.[7] On December 4, 2002, Defendant removed the case to this Court. On February 2, 2007, Plaintiff moved to remand the case back to the state court.

II. DISCUSSION

A. Jurisdiction

Before addressing the merits of this case, this Court must determine that it has jurisdiction over the subject matter of the instant action.

1. Standard of Federal Jurisdiction

"Federal courts are courts of limited jurisdiction. They possess only that power authorized by Constitution and statute." *Kokkonen v. Guardian Life Ins. Co.*, 511 U.S. 375, 377 (1994). If a federal court takes action in a dispute over which it lacks subject matter jurisdiction, that action is a nullity. *See Am. Fire & Cas. Co. v. Finn*, 341 U.S. 6, 17-18 (1951); *Hart v. Terminex Int'l*, 336 F.3d 541, 541-42 (7th Cir. 2003) (stating that it was "regrettable" that the

[6] There was no argument made, nor authority cited in Plaintiff's brief regarding her negligence claim; therefore, it is considered to be waived.

[7] In her Motion, Plaintiff acknowledged that the Nationwide Class Action Settlement Agreement that she entered into with Defendant prohibits her from asserting a cause of action based on fraud or a deceptive trade practices act. The Court will, therefore, dismiss these claims, with prejudice, against Defendant.

case had to be dismissed for lack of subject matter jurisdiction "rendering everything that has occurred in [the] eight years [of litigation] a nullity"). A claim may be removed to federal court only if it could have been brought in federal court originally; thus, the diversity and amount in controversy requirements of 28 U.S.C. § 1332 must be met, or the claim must be based upon a federal question pursuant to 28 U.S.C. § 1331. *Peters v. Union Pac. R.R. Co.*, 80 F.3d 257, 260 (8th Cir. 1996). The party invoking jurisdiction bears the burden of proof that the prerequisites to jurisdiction are satisfied. *In re Bus. Men's Assurance Co.*, 992 F.2d 181, 183 (8th Cir. 1993).

Because the removal statutes impede upon states' rights to resolve controversies in their own courts, such statutes must be strictly construed. *Nichols v. Harbor Venture, Inc.*, 284 F.3d 857, 861 (8th Cir. 2002). Although a defendant has a statutory right to remove when jurisdiction is proper, the plaintiff remains the master of the claim and any doubts about the propriety of removal are resolved in favor of remand. *See In re Bus. Men's*, 992 F.2d at 183; *McHugh v. Physicians Health Plan of Greater St. Louis*, 953 F. Supp. 296, 299 (E.D. Mo. 1997). If "at any time before final judgment it appears that the district court lacks subject matter jurisdiction," the case must be remanded to the state court from which it was removed. 28 U.S.C. § 1447(c).

One basis for removal is diversity of citizenship pursuant to 28 U.S.C. § 1332. Jurisdiction under § 1332 requires (1) complete diversity of citizenship and (2) a minimum amount in controversy in excess of $75,000. 28 U.S.C. § 1332. The Court must find complete diversity before it exercises jurisdiction in this case. *Strawbridge v. Curtiss*, 7 U.S. 267 (1806). That is, a court must conclude the plaintiff is from a state that is different from the defendant. *Id.* A defendant may remove a civil action from a state court to a federal court on the basis of diversity jurisdiction only if none of the properly joined defendants are citizens of the state in

which the original action was filed. 28 U.S.C. § 1441(b); *Pender v. Bell Asbestos Mines, Ltd.*, 46 F. Supp. 2d 937, 939 (E.D. Mo. 1999).

2. Discussion

In support of her Motion to Remand, Plaintiff claims that complete diversity between the parties did not exist when the Petition was filed in the Circuit Court of the City of St. Louis because both Plaintiff and Defendant Wyeth-Ayerst Laboratories Company ("WALCO") were citizens of the Commonwealth of Pennsylvania.[8] Plaintiff argues that the merger between WALCO and AHPSHC was effected solely to create diversity in this action, in violation of 28 U.S.C. § 1359.

On February 9, 2007, the Court held a hearing on Plaintiff's Motion to Remand and the Court heard arguments from the parties on the Motion. On February 14, 2007, this Court ordered Defendant to submit evidence and supplemental briefing establishing a legitimate business reason for the merger between WALCO and AHPSHC. This Court determined, in its February 14 Order that, "if Defendant meets its burden, the citizenship of AHPSHC (Delaware) will apply to determine whether this Court has diversity jurisdiction over this action. *See* 8 Del. Code Ann Tit. 8, §259;[9] *see also Hoefferle Truck Sales, Inc., v. Divco-Wayne Corp.*, 523 F.2d 543, 549 (7th

[8] The parties dispute whether WALCO has its principal place of business in Pennsylvania. Defendant argues that WALCO had its principal place of business in New Jersey. While Plaintiff argues that WALCO had its principal place of business in Pennsylvania, it is not necessary for the Court to rule on this issue. *See* 8 Del. Code Ann. tit. 8, §259 (2007).

[9] Relevant Delaware law provides: "When any merger or consolidation shall have become effective under this chapter, for all purposes of the laws of this State the separate existence of all the constituent corporations, or of all such constituent corporations except the one into which the other or others such constituent corporations have been merged, as the case may be, shall cease and the constituent corporations shall become a new corporation or be merged into 1 of such

Cir. 1975) (citing *Akwell Corp v. Eiger*, 141 F. Supp. 19, 21 (S.D.N.Y. 1956)) ("after a foreign corporation merges into a Delaware corporation, the surviving corporation for diversity jurisdiction is a citizen of Delaware."). In opposing the Motion, Defendant states that the merger at issue was effected not to create diversity in this action, but as part of Wyeth's overall business reorganization.[10]

Under the provisions of § 1359, "[a] district court shall not have jurisdiction of a civil action in which any party, by assignment or otherwise, has been improperly or collusively made or joined to invoke the jurisdiction of such court." By enacting §1359, "Congress sought to assure that ordinary contract and tort litigation is not diverted to the federal courts by litigants using devices to create the appearance, but not the substance, of federal diversity jurisdiction." *Gross v. Houghland*, 712 F.2d 1034, 1037 (6th Cir. 1983) (citing *Kramer v. Caribbean Mills*, 394, U.S. 823, 838-39 (1969)). Thus, courts have concluded that "a party has been improperly or collusively made or joined," 28 U.S.C. §1359, when the primary aim of the transaction is to manufacture federal jurisdiction. *Id*.

Here, Defendant is required to demonstrate a legitimate, non-pretextual reason for the merger between WALCO and AHPSHC. *See Yokeno v. Mafnas*, 973 F.2d 803, 810 (9th Cir. 1992) ("simply articulating a business reason is insufficient; the burden of proof is with the party asserting diversity to establish that the reason is legitimate and not pretexual."). The business

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corporations, as the case may be ...." tit. 8, §259.

[10] Defendant states that prior to the merger, both WALCO and AHPSHC were subsidiaries of American Home Products Corporation ("AHP "). AHP changed its name to Wyeth on March 11, 2002. Plaintiff does not dispute Defendant's claim.

reason must be sufficiently compelling that the merger would have been made absent the purpose of gaining a federal forum. *Id*. at 811.

The Court believes that Defendant has established that a legitimate business reason existed for the merger at issue (unconnected with acquisition of diversity jurisdiction). Defendant has submitted an affidavit from their senior tax counsel, Kevin Giordano ("Mr. Giordano"). Mr. Giordano explains that in the late 1980s, AHP began analyzing its business structure. AHP decided to divest some of its subsidiaries unrelated to healthcare and streamline its operational and accounting systems. Mr. Giordano states that by the year 1999, AHP had 78 domestic subsidiaries, and as a result of its streamlining efforts, Wyeth reduced this total to 45 domestic subsidiaries by the end of 2005. Mr. Giordano further states that WALCO's merger into AHPSHC was a part of this streamlining process and eliminated the need to file approximately 586 state and local tax returns.

The Court finds that Defendant has presented legitimate, non-jurisdictional business reasons, under §1359, for the merger between WALCO and AHPSHC; reorganizing Wyeth's corporate structure and reducing tax filings. *See Mother Bertha Music, Inc. v. Trio Music Co.*, 717 F. Supp. 157, 160 (S.D.N.Y. 1989) (finding overall business reorganization and tax planning as facially valid reasons for corporation's formation, other than the creation of diversity jurisdiction, under §1359); *see also Prudential Oil Corp. v. Phillips Petroleum Co.*, 546 F.2d 469, 477 (2d Cir. 1976) (saving in taxes or operational costs; eligibility for state licenses or other benefits are valid business reasons for parent company's change of state of incorporation of subsidiary, under §1359). Furthermore, the Court finds particularly persuasive Defendant's argument that Wyeth currently maintains other subsidiaries in Pennsylvania and routinely defends

diet drug cases against them in Pennsylvania state court. Thus, the Court concludes that it has jurisdiction over the present action, as Defendant has carried its burden of demonstrating diversity.[11]

B. Motion for Summary Judgment

1. Summary Judgment Standard

Pursuant to Federal Rule of Civil Procedure 56(c), a court may grant a motion for summary judgment only if all of the information before the court shows "there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). The United States Supreme Court has noted that "summary judgment procedure is properly regarded not as a disfavored procedural shortcut, but rather as an integral part of the federal rules as a whole, which are designed to 'secure the just, speedy and inexpensive determination of every action.'" *Id.* at 327 (quoting Fed. R. Civ. P. 1). "By its terms, [Rule 56(c)(1)] provides that the mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for judgment; the requirement is that there be no *genuine* issue of *material* fact." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). Material facts are those "that

[11] Plaintiff cites to *Pac Finance Corporation. v. Patterson Dental Co.*, No. 84-1238, 1985 U.S. District Lexis 21696, at *7 (E.D. Pa. March 18, 1985), for the proposition that Defendant has failed to meet their burden of establishing a legitimate business reason for the merger at issue. The Court finds that *Pac Finance Corporation* is distinguishable from the facts in this case. In *Pac Finance Corporation*, the court found that the merger in question was a sham because all of the assets transferred during the merger, related to the matter before the court. *See Id.* at *6 n.4. Here, Defendant claims that Wyeth divested or merged various subsidiaries, unrelated to the instant controversy, in order to focus on three business areas, organized in three divisions: prescription pharmaceuticals, animal health and consumer products. Plaintiff has not disputed Defendant's claim.

might affect the outcome of the suit under the governing law," and a genuine material fact is one such that "a reasonable jury could return a verdict for the nonmoving party." *Id*.

If the non-moving party has failed to "make a showing sufficient to establish the existence of an element essential to that party's case, . . . there can be 'no genuine issue as to any material fact,' since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." *Celotex*, 477 U.S. at 322-23. "Thus, where the moving party can point to the absence of any evidence satisfying a necessary element of a claim, such as damages, and the non-moving party fails to produce any such evidence, summary judgment is properly entered." *Meterlogic, Inc. v. KLT, Inc.*, 368 F.3d 1017, 1018 (8th Cir. 2004).

The initial burden of proof in a motion for summary judgment is placed on the moving party to establish the non-existence of any genuine issue of fact that is material to a judgment in its favor. *City of Mt. Pleasant, Iowa v. Associated Elec. Co-op., Inc.*, 838 F.2d 268, 273 (8th Cir. 1988). Once this burden is discharged, if the record does, in fact, bear out that no genuine dispute exists, the burden then shifts to the non-moving party who must set forth affirmative evidence and specific facts showing there is a genuine dispute on that issue. *Anderson*, 477 U.S. at 249. When the burden shifts, the non-moving party may not rest on the allegations in its pleadings, but by affidavit and other evidence must set forth specific facts showing that a genuine issue of material fact exists. Fed. R. Civ. P. 56(e); *Stone Motor Co. v. Gen. Motors Corp.*, 293 F.3d 456, 465 (8th Cir. 2002). To meet its burden, the non-moving party must "do more than simply show there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). In fact, the non-moving party must show

there is sufficient evidence favoring the non-moving party which would enable a jury to return a verdict for it. *Anderson*, 477 U.S. at 249; *Celotex*, 477 U.S. at 324. "If the non-moving party fails to produce such evidence, summary judgment is proper." *Olson v. Pennzoil Co.*, 943 F.2d 881, 883 (8th Cir. 1991).

2. Failure to Warn[12]

a. Applicability of the Learned Intermediary Doctrine under Iowa Law

The parties agree that Iowa substantive law controls this products liability diversity case. Before analyzing the substance of Defendant's motion for summary judgment, the Court must determine to what extent the learned intermediary doctrine governs Plaintiff's claims, under Iowa law. Central to all of Plaintiff's claims is the assertion that Defendant failed to adequately warn consumers and their prescribing physicians or healthcare providers about the dangerous side effects associated with the diet drugs.

As a general rule, the manufacturer of a product has a duty to warn the user of dangers inherent in that product under the theories of strict liability, negligence, and breach of warranty. *Hill v. Searle Laboratories, Div. of Searle Pharmaceuticals, Inc.*, 884 F.2d 1064, 1070 (8th Cir. 1989). The learned intermediary doctrine provides an exception to this general rule:

> Under the doctrine, a drug manufacturer is excused from warning each patient who receives the product when the manufacturer properly warns the prescribing physician of the product's dangers. Hence, a drug manufacturer's duty to warn consumers about the dangers of its prescription drugs extends only to the

[12] The Iowa Supreme Court has abandoned any distinction between strict liability and negligence in products liability failure-to-warn cases. *See Wright v. Brooke Group*, 652 N.W.2d 159, 166 (2002) (citing *Olson v. Prosoco*, 522 N.W.2d 284, 289 (Iowa 1994)). "[S]uch claims should be submitted under a theory of negligence only." *Id.* Accordingly, the Court will construe Plaintiff's strict liability failure-to-warn claim under a theory of negligence.

> prescribing physician or healthcare provider, who acts as a "learned intermediary" between the manufacturer and the ultimate consumer and assumes responsibility for advising individual patients of the risks associated with the drug. The manufacturer's duty to warn is limited to adequately informing the healthcare provider of any risks associated with the product's use. Thus, a warning to the healthcare provider is deemed a warning to the patient; the manufacturer need not communicate directly with all ultimate users of prescription drugs.

In re Norplant Contraceptive Prods. Liab. Litig., 215 F. Supp. 2d 795, 821 (E.D. Texas 2002) (internal citations and quotations omitted); *see also Ehlis v. Shire Richwood, Inc.*, 367 F.3d 1013,1016 (8th Cir. 2004) (same). Courts have identified the following rationales for the doctrine: 1) states want to preserve the doctor-patient relationship which could be undermined if patients received warnings from drug manufacturers that differed from doctor's warnings; 2) physicians are in a better position to convey information to patients than manufacturers; 3) manufacturers lack an efficient means to communicate warnings to individual consumers; and 4) states are concerned that patients cannot comprehend complex medical information, and it is too burdensome for pharmaceutical companies to translate medical jargon into understandable language. *In re Norplant*, 215 F. Supp. 2d at 815 (internal citations omitted).

The parties disagree as to whether Iowa would adopt the learned intermediary doctrine where the adequacy of a warning with respect to a prescription drug is at issue. After considering the parties arguments, the Court believes that Iowa would adopt the doctrine.

In *In re Norplant*, the court determined that 48 states, the District of Columbia and Puerto Rico apply the learned intermediary doctrine to define a pharmaceutical company's duty to warn of risks associated with the use of a prescription drug. The court cited to Eighth Circuit precedent in determining that the learned intermediary doctrine is a part of Iowa's common law. *See Id*. at 821(citing *Petty v. U.S.*, 740 F.2d 1428, 1440 (8th Cir. 1984)). In *Petty*, the court held

that, under Iowa law, the drug manufacturer's duty to warn extends to the ultimate consumer in a mass immunization context, where there is no learned intermediary.[13] Here, the prescribing physician, Dr. Miller, acted as a learned intermediary between Plaintiff and the drug manufacturer; he assumed the responsibility of advising Plaintiff about the risks associated with the diet drugs. Thus, under *Petty*, Defendant had a duty to warn Dr. Miller of the risk of valvular heart disease. That duty to warn, however, did not extend to Plaintiff.

The Court also observes that the Iowa Supreme Court has adopted §§ 1 and 2 of the Restatement (Third) of Torts: Products Liability, for product defect cases involving manufacturing defects, design defects, and defects based on inadequate instructions or warnings. *See Wright v. Brooke Group Ltd.*, 652 N.W. 2d 159, 169 (Iowa 2002). Section 6 of the Restatement (Third), entitled "Liability of Commercial Seller or Distributer for Harm Caused by Defective Prescription Drugs and Medical Devices," applies the principles of §§ 1 and 2 to the prescription drug and medical device context. Section 6(d) provides:

> A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to: (1) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; or (2) the patient when the manufacturer knows or has reason to know that health-care provider will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.

The policies underlying the language of Section 6(d) are akin to those enunciated by the learned intermediary doctrine. Indeed, the Restatement (Third) has specifically adopted the

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[13] Courts have also declined to apply the learned intermediary doctrine in cases where the drug manufacturer provided information directly to consumers of a prescription drug. *See Perez v. Wyeth Lab., Inc.*, 734 A. 2d 1245 (N.J. 1999). Plaintiff has not presented any evidence that Defendant provided information about the diet drugs directly to consumers.

learned intermediary rule: "[w]arnings and instructions with regard to drugs or medical devices that can be sold legally only pursuant to a prescription are, under the 'learned intermediary' rule, directed to health care providers." *See* Restatement (Third) of Torts: Products Liability, §6, comment e (1998). Consequently, under §6, if the health care provider is in the position to reduce the risks of harm in accordance with the instructions or warnings, then the prescription drug or medical device manufacturer will held liable only when its fails to provide the proper warnings to the health care provider, not the consumer.

Thus, Iowa's adoption of the Restatement (Third) of Torts analytical framework for product defect cases and the overwhelming precedent adopting the learned intermediary doctrine convinces the Court that the Iowa Supreme Court would recognize that the doctrine governs Plaintiff's failure-to-warn claims at issue.[14] Accordingly, the Court finds that, in this case, Defendant was required to warn only Plaintiff's prescribing physician about the risks associated with the diet drugs, not Plaintiff herself.

b. Adequacy of the Warning and Proximate Cause

The Court must next determine whether Plaintiff has presented sufficient evidence to overcome the learned intermediary doctrine. Defendant argues that it adequately warned physicians about the risk of valvular heart disease associated with the diet drugs or that any

[14] The Court declines Defendant's invitation to construe all of Plaintiff's claims as failure-to-warn claims. The Iowa Supreme Court has approved submission of strict liability, negligence and breach of warranty claims in products liability cases. *See Wright*, 652 N.W.2d at 181 (quoting *Lovick v. Wil-Rich*, 588 N.W.2d 688, 698 (Iowa 1999)) (while strict liability, negligence and breach of warranty are distinct theories of recovery, the same facts often give rise to all three claims).

alleged inadequate physician warnings were not the producing cause or proximate cause of Plaintiff's injuries.

To overcome the learned intermediary doctrine, plaintiffs must demonstrate both of the following: (1) that the product warnings given by the drug manufacturer to healthcare providers are inadequate; and (2) that those inadequate warnings were a producing cause of or proximately caused plaintiffs' subsequent injuries. *In re Norplant*, 215 F. Supp. 2d at 821.

In a prescription drug product liability case, an adequate warning is one reasonable under the circumstances. Specifically, the warning must: (1) indicate the scope of the danger; (2) communicate the extent or seriousness of the potential danger; (3) alert a reasonably prudent practitioner to the danger; and (4) be conveyed in a satisfactory manner. *Ehlis*, 233 F. Supp. 2d at 1196. Any disputes in the adequacy of the warning is usually resolved by the trier of fact. *Colacicco v. Apotex*, Inc., 432 F. Supp. 2d 514, 547 (E.D. Pa. 2006).

For plaintiffs to prove that the allegedly "deficient warnings proximately caused, or, with respect to strict products liability failure to warn claims, were a producing cause of plaintiffs' injuries, even assuming the warnings are inadequate, plaintiffs must show that a proper warning would have changed the decision of the treating physician, i.e. that but for the inadequate warning, the treating physician would not have used or prescribed the product." *In re Norplant*, 215 F. Supp. 2d at 821. Thus, the causal link between a patient's injury and the alleged failure to warn is broken when evidence is presented that the prescribing physician would have continued to prescribe the medication for the patient even if he had been provided with adequate warnings. *Stafford v. Wyeth*, 411 F. Supp. 2d 1318, 1320 (W.D. Mo. 2006).

As evidence that health care providers were adequately warned of the diet drugs potential

adverse side effects, Defendant points to reports of valvular heart disease in women treated for obesity with a combination of fenfluramine and phentermine, published by the Mayo Clinic in August 1997.[15] Defendant also notes that, in July 1997, the FDA issued a public health advisory informing the medical community of the Mayo Clinic Report's findings. Finally, Defendant claims that it revised the diet drugs' warning language indicating the risk of valvular heart disease and primary pulmonary hypertension. This revision was approved by the FDA in August 1997.

Plaintiff argues that Defendant should have first warned of the risk of valvular heart disease associated with the diet drugs in 1994, instead of in 1997. Plaintiff claims that Defendant received "adverse drug event reports" from 1994 to 1996, regarding valvular heart disease in patients using the diet drugs, but failed to warn the medical community of such reports. Plaintiff further claims that in 1996, when she was prescribed fenfluramine and dexfenfluramine, the diet drugs' package insert did not indicate that there was an increased risk of valvular heart disease. Finally, Plaintiff argues that the Mayo Clinic Report would not lead a reasonably prudent practitioner to conclude that there is a statistical association between the use of the drugs and valvular regurgitation. Plaintiff offers the testimony of Dr. Miller for this proposition. In his deposition, Dr. Miller testified that he viewed the report as an "eye opener and something to look

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[15] The Mayo Clinic Report, entitled "Valvular Heart Disease Associated with Fenfluramine-Phentermine," advised that twenty-four women, evaluated a certain number of months after the initiation of fenfluramine-phentermine therapy, demonstrated unusual valvular morphology and regurgitation. The report concluded that "these cases should arouse concern that [fenfluramine -phentermine therapy] has important implications regarding valvular heart disease. Prospective studies of this association will be required to validate the possibility that this combination of medications may cause valvular heart disease.... Candidates for fenfluramine-phentermine therapy should be informed about serious potential adverse side effects, including pulmonary hypertension and valvular heart disease." *See* Pl.'s Response in Opp'n to Def.'s Mot. for Summ. J. Ex. E.

at seriously, but [thought] that it needed follow-up work to assess what the general risk was and whether the drug needed to be removed from practice." Dr. Miller further testified that the diet drugs were effective and that his practice group did not know the relative risks well enough to discontinue their use.

The Court believes that Plaintiff has presented evidence to show that Defendant failed to adequately warn the medical community, as early as 1994, that the diet drugs could cause valvular heart disease. However, the record contains insufficient evidence to create a genuine issue of material fact as to whether Defendant's alleged failure to warn was the proximate cause of Plaintiff's injury. Plaintiff has failed to present any evidence that Dr. Miller would not have prescribed fenfluramine and dexfenfluramine if Defendant had provided adequate warnings in 1996.

The Court believes that adequate warnings were provided to the medical community as of July 1997 regarding the increased risk of valvular heart disease. In August 1997, the Mayo Clinic Report advised that candidates for diet drug therapy should be informed about serious potential adverse effects, including pulmonary hypertension and valvular heart disease. In July 1997, the FDA's public health advisory similarly noted the seriousness of the reported valvular heart disease and its rare occurrence in otherwise healthy obese women. Finally, though Dr. Miller questioned the relative risks of the adverse effects associated with the diet drugs, he characterized the Mayo Clinic Report as a "eye-opener and something to look at seriously."

Further, it is undisputed that, in 1997, Dr. Miller continued to prescribe the diet drugs after he obtained knowledge about the increased risk of valvular heart disease. It is, therefore, reasonable to infer that had Dr. Miller read and heeded the warnings, in 1996, he would have

continued to prescribe the diet drugs at that time as well. Plaintiff has not provided any evidence to the contrary. Thus, the Court concludes that the causal link between Plaintiff's injury and the alleged failure to warn is broken because the evidence indicates that Dr. Miller would have continued to prescribe the diet drugs even if he had been provided with adequate warnings in 1996. *See Stafford*, 411 F. Supp. 2d at 1320. Thus, summary judgment in favor of Defendant on Plaintiff's failure-to-warn claim is appropriate.

3. Design Defect[16]

As noted previously, Iowa has adopted the Restatement (Third) of Torts: Products Liability for product defect cases. Section 6(c) of the Product Restatement provides:

> A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients.

The comments to § 6 elaborate on the requirements for establishing defective design of a prescription drug or medical device under §6 (c): "a drug is defectively designed only when it provides no net benefit to any class of patients .... [T]he drug or device [has] so little merit compared with its risks that reasonable health-care providers, possessing knowledge of risks that were known or reasonably should have been known, would not have prescribed the drug or device for any class of patients. Thus, a prescription drug or medical device that has usefulness to any class of patients is not defective in design even if it is harmful to other patients." *See*

[16] The Iowa Supreme Court has declined to attach any doctrinal label to design defect cases. *See Wright*, 652 N.W.2d at 169 ("we prefer to label a claim based on defective product design as a design defect claim without reference to strict liability or negligence.").

Restatement (Third) of Torts: Products Liability, §6, comment b.

Applying this standard, the Court finds that Plaintiff has failed to establish a genuine issue of material fact on her design defect claims at issue. Plaintiff has not presented any evidence that reasonable health-care providers, knowing the risks and benefits, would not have prescribed phentermine, fenfluramine or dexfenfluramine to any class of patients. Furthermore, Plaintiff does not dispute Defendant's evidence supporting its position that Plaintiff cannot meet the requirements under §6.

One of Defendant's experts, Kenneth Rictor, M.D. ("Dr. Rictor"), a board-certified family physician specializing in the treatment of obesity, testified:

> Weighing the risks and benefits of Pondimin in combination with phentermine and of Redux as known in the medical community at the time they were available for prescription and as I know them today, I would prescribe those medications for appropriate patients. The risks of obesity for some patients are greater than the risks of those medications.

See Def.'s Mot. for Summ. J. Ex. Q. Plaintiff has not disputed Dr. Rictor's testimony. Further, as noted earlier, Dr. Miller testified that his practice group continued to prescribe the diet drugs after obtaining knowledge of the increased risk of valvular heart disease. Accordingly, summary judgment in favor of Defendant will be granted on Plaintiff's design defect claims.

4. Breach of Warranty

Under Iowa law, an express warranty is created by an affirmation or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain or any description of the goods which is made part of the basis of the bargain. *See* Iowa Code § 554.2313 (2005); *see also Moore v. Vanderloo*, 386 N.W. 2d 108, 112 (Iowa Ct. App. 1986). A manufacturer may also breach its implied warranty of merchantability, based on lack of fitness for

ordinary purposes, by failing to provide adequate instructions or warnings. *See* Iowa Code § 554.2314 (2)(c) (1999); *see also Wright*, 652 N.W.2d at 181. However, warranty liability under §554.2314(2)(c) requires proof of a product defect as defined in Products Restatement (Third) of Torts §2. *See Wright*, 652 N.W.2d at 182.

To establish that a genuine issue of material fact exists on her breach of express warranty claim, Plaintiff must present evidence to show that Defendant made affirmations of fact to her regarding the diet drugs. *See Stoffel v. Thermogas Co.*, 998 F. Supp. 1021, 1029 (N.D. Iowa 1997) (granting summary judgment in favor of defendant on plaintiff's breach of express warranty claim where defendant made no affirmations of fact to plaintiff). By Plaintiff's own account, she never read any material regarding fenfluramine or dexfenfluramine or the drugs' side effects, read any advertising in making her decision to take the drugs, or relied on any written or oral statements from Defendant in deciding to buy the drugs. *See* Def.'s Mot. for Summ. J. Ex. R. Without such reliance, Plaintiff cannot prevail on her breach of express warranty claim and summary judgment must be granted in Defendant's favor.

Likewise, because this Court has determined that Plaintiff cannot prevail on her design defect claim, summary judgment in favor of Defendant must also be granted on Plaintiff's implied warranty of merchantability claim. *See Wright*, 652 N.W.2d at 182.

Accordingly,

IT IS HEREBY ORDERED that Plaintiff Ember Madsen's Motion for Remand [doc. #51] is **DENIED**.

IT IS FURTHER ORDERED that Defendant American Home Products Corporation's Motion for Summary Judgment [doc. #40] is **GRANTED**.

IT IF FURTHER ORDERED that any additional pending motions are **DENIED**, **as moot**.

An appropriate order of judgment will accompany this Order.

Dated this 7th day of March, 2007.

E. RICHARD WEBBER
UNITED STATES DISTRICT JUDGE